

APR 29 1997 K970204

1.2 Safety and Effectiveness Summary

BIOTRONIK BK Series Sealing Caps are single-component silicone devices, designed to be safe and effective through design functionality, simplicity and material biocompatibility.

BK Sealing Caps are designed to be chronically implantable. The material of construction is Silopren LSR-4070, which has been extensively used by BIOTRONIK in cardiac pacing lead designs. FDA has reviewed and cleared this material in the following submissions:

Physios CTM 01 Pulse Generator and ELC XX-UP Epicardial Lead

IDE #G960045

Approved August 22, 1996

TIR and TIJ Endocardial Leads

510(k) #K953044

Cleared September 27, 1996

Dromos DR and SR Pulse Generators

PMA #P950037

Approved October 11, 1996.

Silopren LSR-4070 has been thoroughly tested for biocompatibility, and is commonly used in many market-released Class III products, including pacemaker and defibrillator leads and their accessories. Acute and chronic biocompatibility tests have been performed, as well as long-term implantation studies.

BK Sealing Caps are tested for ease of use, ability to withstand ligature application, potential fluid leakage, and adherence to IS-1 standards. Packaging and transportation durability as well as sterilization validation have been performed to ensure the quality and sterility of the delivered product.

All production and biocompatibility test results were within specifications; therefore, when the currently proposed BK Sealing Caps are in use, the patient will be exposed to no risks in excess of those experienced by patients using comparable competitor sealing caps manufactured and distributed in the United States, or older model BIOTRONIK sealing caps. Complications arising from usage may include body rejection phenomena, fibrosis, displacement, infection, and erosion. BIOTRONIK is not aware of any other adverse safety and effectiveness data on these accessories.

In accordance with the Safe Medical Device Act of 1990, a thorough literature search for adverse safety and effectiveness data on pacemaker lead sealing caps was performed. The search yielded no articles related to the safety of pacemaker lead sealing caps.